PIH67
A REVIEW OF PATIENT-REPORTED OUTCOME ORPHAN DRUG LABELS IN THE UNITED STATES FROM JANUARY 2006-SEPTEMBER 2013: ANALYSIS OF EVIDENCE FOR ORPHAN DRUG PRO LABEL CLAIMS
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OBJECTIVES: Previous reviews of patient-reported outcome (PRO) label claims did not distinguish products with orphan designation. Prior analyses suggest less evidence is required for orphan drug approvals compared to non-orphan drugs. This study aimed to identify orphan drug products approved by the US Food and Drug Administration (FDA) between 2006 and 2013, prevalence of PRO label claims for these products, and evidence supporting PRO claim approval. **METHODS:** Using the Drugs@FDA database, new molecular entities and biologic licensed agents approved between January 2006 and September 2013 with orphan review classification were identified, with subsequent label review. For products with PRO label claims, medical and summary review sections from FDA drug approval packages were reviewed to identify reviewing division, indication, review designation (priority, standard), PRO endpoint status, PRO measure type, number of phase 3 trials supporting claims, and PRO-related SEALD comments. Descriptive data were recorded in Microsoft Excel; frequency of measured characteristics was analyzed. **RESULTS:** Of 43 orphan products identified, 5 (12%) included PRO label claims. Five orphan products achieved 7 PRO claims. Priority and standard review prevalence were similar (44% vs. 40%, respectively) for orphan products; the majority (4 of 5) of products with PRO claims were priority review. A slight majority (60%; 3 of 5 orphan products) included PRO claims supported by ≤ 1 phase 3 trial. Signs/symptoms measures and secondary PRO endpoints were most common (57% each). FDA reviewing division varied. One product received PRO-related SEALD comments. **CONCLUSIONS:** For the time period evaluated, orphan products rarely included a PRO label claim. These claims may not be needed for orphan product differentiation to the degree that they are for non-orphan products. PRO claims achieved for orphan products appear to require less supporting evidence for approval than non-orphan products, consistent with orphan drug approval expectations but in contrast to FDA PRO guidance criteria.

PIH68
HEALTH OUTCOMES ASSOCIATED WITH THE USE OF PROHORMONE NUTRITIONAL SUPPLEMENTS
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OBJECTIVES: Anabolic prohormones, similar to anabolic-androgenic steroids, are sold as dietary supplements in the United States. There is very little known about the health outcomes associated with exposure to prohormones. The objective of this study was to assess health outcomes and user perceptions about health outcomes associated with prohormone use. **METHODS:** A self-administered survey was developed and deployed via two e-forums dedicated to prohormone use. Questions included information about health outcomes, beliefs about the commonality of side effects in users, and prohormone use characteristics including number of substances taken, number of cycles completed in a year, and taking the recommended or excess dosage. Outcomes were correlated with beliefs. Logistic regressions were used to measure the association between dose categories and self-reported outcomes. A multiple risk factor analysis looked at the association between higher than average number of self-reported outcomes and several combined risk indicators. Combined risk indicators comprised of taking above recommended dose merged in combination with highest number of substances per cycle, highest number of cycles per year and having also taken AAS in the last year, respectively. **RESULTS:** Eighteen self-reported outcomes were generated from 65 responders. Users reported an average of 2.49 (SD-0.60) outcomes in their last prohormone cycle. Correlations showed those who experienced no outcomes believe adverse events are uncommon (R=0.26, P=0.04). Conversely, those who experienced the highest number of outcomes are not correlated with the belief that outcomes are common (R=0.17. P=0.16). No outcome was significantly associated with taking more than the recommended dose. Multiple risks showed no significant association with an above average number of reported outcomes. **CONCLUSIONS:** This study is a pilot into an understudied population. Despite having a small sample, this study is the first of its kind in compiling self-reported outcomes in prohormone users.

PIH69
ADVERSE DRUG REACTION REPORTING SYSTEM AT DIFFERENT HOSPITALS OF LAHORE - AN EVALUATION AND PATIENT OUTCOME ANALYSIS
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OBJECTIVES: ADRs are known to be a major cause of morbidity and mortality. However, only a very little proportion is reported. ADRs contribute to the incidence of adverse events, resulting in increased health care costs. **METHODS:** The first part of this project was to review the ADRs reporting system in Pakistani hospitals, to determine the factors contributing to the ADR reporting rate and benchmark with developed countries. Data was collected by self-administered questionnaire. 24 (80%) hospitals have no proper ADRs system; five (16.7%) hospitals are targeting few of the drugs for ADRs reporting while only one (3.3%) hospital has a proper ADRs policy including online reporting system as well. Only seven (23.3%) hospitals have a policy of ADRs reporting. The next part of the project was a survey of 84 doctors and 52 Pharmacists selected from Lahore, Pakistan to evaluate their involvement, understanding and reasons for reporting ADRs. A self-administered questionnaire was used to collect the data. **RESULTS:** Response rate obtained for the doctors was (39.3% n=33) and (67.3% n=35) for hospital pharmacists. Thirty three (39.3%) doctors and thirty four (65.4%) pharmacists knew how to report ADRs within the hospital while 9 (10.7%) doctors and 13 (25%) Pharmacists knew about the ADRs reporting to Ministry of Health. Factors that would encourage respondents to report ADRs included seriousness of reaction (75.8%), unusual reaction (63.6%), reaction to a new product (66.6%) and confidence in the diagnosis of ADR (31.5%). Similarly, the discouraging factors are uncertain association (65.7%), awareness (57.6%), and concern about legal liability (51.4%). **CONCLUSIONS:** It is observed that awareness of ADRs program need special attention with some concrete steps should be taken for the improvement of ADRs system in Pakistan. Continuing medical education, training and integration of ADRs reporting into the clinical activities would definitely improve the patient outcome.

PIH70
ASSESSMENT OF HEALTH STATES AND ERECTILE DYSFUNCTION-ASSOCIATED QUALITY OF LIFE AMONG ADULT UNITED STATES MALES AND UNITED STATES FEMALES WITH MALE PARTNERS
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OBJECTIVES: This study assessed the quality of life associated with erectile dysfunction (ED) among the U.S. adult population both among diagnosed ED sufferers and non-sufferers. **METHODS:** A representative (U.S.) sample of 1,000 adults (502 males, 498 females) completed an online survey about their own (for men) or partner's (for women in a heterosexual relationship) overall and erectile function health states and quality of life. Health states utilities were measured using both SG and VAS questions (counterbalanced order). **RESULTS:** 11.3% of males report having been diagnosed with ED and 6.4% of females report that their male partner has been diagnosed. Overall, the SG and VAS measures yield very similar but not identical utility estimates for the ED health state. The mean utility estimates across all eligible respondents are 0.41 (0-1 scale) for the SG and 0.44 for the VAS. Looking just at SG, males have lower utility on average (0.37) for the ED health state than do females for their partner's ED health state and there was no difference between males who are healthy and those diagnosed with ED. Women whose partners are healthy express lower utility for the ED health state (described as "significant difficulty in achieving an erection/penis gets hard but not hard enough for penetration") than women with a partner diagnosed with ED. Younger respondents also have lower utility for the ED state than older respondents, and for the VAS the utility function across 5 levels of ED is linear. **CONCLUSIONS:** The fact that males who have not been diagnosed with ED have the same utility for the ED health state as those who have been diagnosed indicates that otherwise healthy males accurately anticipate quality of life decline associated with ED. Females with a diagnosed partner seem more willing to accept living with that partner's ED health state.

PIH72
SPONSORING SPANISH LANGUAGE TRANSLATIONS IN UNITED STATES-BASED CLINICAL TRIALS
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OBJECTIVES: The accuracy of clinical trial data can be jeopardized if the translations used in the study are not regionally appropriate, particularly if the COAs (Clinical Outcomes Assessments) record direct feedback from patients whose first language is not English. Ensuring regional sensitivity in translations can be difficult in countries like the United States, where four major dialect groups dominate the Spanish influence. The purpose of this poster is to review best practices for conducting linguistic validation for US-based sites to ensure the most appropriate Spanish language is used. **METHODS:** Past studies that required US Spanish were reviewed to analyze specific selections and locations of Spanish-speaking patients. Consideration was given to studies incorporating multiple site locations around the country, as well as to studies targeting a specific region. **RESULTS:** US Spanish translations yielded the best results when site location was communicated to the linguistic validation provider. When this information is not available at project commencement, it is necessary to consider the array of national backgrounds and subsequent cultural correlations that are present throughout the US when selecting translators and cognitive interviewing respondents. When site locations were throughout the US, the most inclusive and universal US Spanish was achieved with the following cognitive debriefing recruitment formula for a 5 respondent interview: 2 Mexican respondents, 1 South American respondent, 1 Central American respondent, and 1 Caribbean respondent. If site locations are being concentrated in one area, selecting a team that represents the largest population in that region is ideal. **CONCLUSIONS:** Determining US site location prior to translation is recommended to ensure a more comprehensive translation that is tailored toward the target population, therefore yielding the most accurate responses. If sites have not been confirmed within the US, a recruitment formula developed to account for major Spanish populations in the US is recommended.

PIH73
STRESS (PERCEIVED AND ACCULTURATIVE) AND HEALTH RELATED QUALITY OF LIFE AMONG STUDENTS IN THE ISPOR STUDENT NETWORK: A PILOT STUDY
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OBJECTIVES: The objective of this pilot study was to investigate the associations among perceived stress, acculturative stress, coping mechanisms, and health-related quality-of-life of graduate students. **METHODS:** A cross-sectional, self-administered questionnaire was distributed to UT-ISPOR graduate students. Participants were recruited using an email cover letter sent through the UT-ISPOR mailing list. Willing participants were asked to complete the survey (either web-based or paper-pencil method). The questionnaire consisted of five sections: 1) SF-12 Health Survey (mental component summary [MCS], and physical component summary [PCS]); In the general population, these scores have a mean of 50 and a standard deviation of 10, with higher scores correlating with better HRQoL; 2) Graduate Stress Inventory-Revised (GSI-R) Scale (higher scores = higher stress) ;